UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,349	11/06/2006	Dianna Bowles	14300.1008	2021

20601 7590 11/24/2008

SPECKMAN LAW GROUP PLLC
1201 THIRD AVENUE, SUITE 330
SEATTLE, WA 98101

EXAMINER	
PAGE, BRENT T	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
11/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,349	BOWLES ET AL.	
	Examiner	Art Unit	
	BRENT PAGE	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *10,14,20,26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-13, 15-19, 21-25 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Reply filed on 08/12/2008 in response to the restriction requirement mailed out on 06/16/2008 is hereby acknowledged. Applicants have elected Group I, and SEQ ID NO:1.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-9, 11-13, 15-19, 21-25 and 28 read on the elected invention and are examined herein on the merits. Claims 10, 14, 20 and 26-27 are withdrawn as being drawn to nonelected subject matter.

Claim Objections

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 fails to further limit claim 8.

Double Patenting

Applicant is advised that should claims 12, 15, and 25 be found allowable, claims 13, 19 and 28, respectively will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to

object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 8-9, 11-13, 15-19, 21-25 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic cell comprising a heterologous nucleic acid comprising SEQ ID NO:1 and the regulation thereof in a plant cell, does not reasonably provide enablement for any sequence that hybridizes to SEQ ID NO:1 or any degenerate sequence for regulation in any species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to any transgenic cell wherein the genome comprises any sequence that is degenerate from or hybridizes to SEQ ID NO:1, wherein the nucleic acid is down-regulated to reduce glucosyltransferase activity.

In contrast, the specification only provides guidance for the generation of a construct comprising UGT72E1 and UGT72E3 fragments and the transformation of Arabidopsis with the construct. No demonstration of success is indicated in

the specification and no guidance is given as to what is required of a sequence to either silence or to successfully encode a glucosyltransferase.

The function of all glucosyltransferases and derivatives thereof is not known and therefore unpredictable. In a review of glucosyltransferases, Lorenc-Kukula et al (2004 Cellular and Molecular Biology Letter 9:935-946) discuss the wide range of glucosyltransferases, the wide range of functions and the unpredictability of function. Since glucosyltransferases have some sequence similarities, any glucosyltransferase would be expected to hybridize under unspecified conditions, particularly where glucosyltransferase genes are identified based on hybridization. The review shows that glucosyltransferases have a wide range of functions and that the function of a particular glucosyltransferase is not predictable simply based on nucleic acid sequence, or simply based on similarity to another gene with glucsyltransferase activity. Lorenc-Kukula state "Although there are an increasing number of identified UGTs, their exact physiological significance has yet to be described" (see page 936 2nd paragraph). Further, the specification and the prior art does not provide sufficient guidance as to which particular sequences are required for either silencing or for the expression/function of a glycosyltransferase wherein the sequence varies from SEQ ID NO:1.

Given the state of the art and the disclosure by Lorenc-Kukula et al, it would be undue experimentation for one of skill in the art to construct and evaluate all degenerate and hybridizing sequences of SEQ ID NO:1 for their

function in either silencing or in expressing glucosyltransferase in a transgenic cell.

Claims 11-13, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a multitude of sequences and degenerate sequences that wherein the expression of said sequences are down-regulated to reduce glucosyltransferase activity in a transgenic cell.

In contrast the specification only describes SEQ ID NO:1 and the generation of a construct comprising UGT72E1 and UGT72E3 fragments for the down-regulation of glucosyltransferase activity. The specification does not describe any other sequences that lead to the down-regulation of glucosyltransferase activity, nor does the specification describe what structures would be required for a any such degenerate sequence to function as a down-regulator of glucosyltransferase activity. Thus, Applicants do not have adequate written description over the full scope of the claims.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559,

1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties".

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11-13, 15-19, 21-25 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a nucleic acid sequence which hybridizes to the sequence in (i) above and which glucosylates at least one monolignol. It is unclear how the nucleic acid molecule may glucosylate or glycosylate a monolignol directly. Any correction must avoid introducing New Matter.

Claim 3 recites the limitation "wherein said monolignol is coniferyl alcohol" in lines 1 and 2 referring to the monolignol of claim 2. There is insufficient antecedent basis for this limitation in the claim. Claim 2 recites the limitation that the monolignol must be selected from the "group consisting of; p-coumaryl

aldehyde, coniferyl aldehyde and sinapyl aldehyde" a group that does not contain coniferyl alcohol, thus lacking antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7 rejected under 35 U.S.C. 102(b) as being anticipated by Reiss et al (US Patent 6583336).

The claims are drawn to any transgenic plant cell comprising SEQ ID NO:1. Any transgenic Arabidopsis plant cell meets the limitation of these claims since SEQ ID NO:1 was isolated from Arabidopsis and would therefore be expected to comprise SEQ ID NO:1 without necessarily being transformed with SEQ ID NO:1.

Reiss et al teach a transgenic Arabidopsis cell (see claims 1 and 2) which would inherently comprise SEQ ID NO:1.

Applicant may wish to state that SEQ ID NO:1 is heterologous to the transformed plant cell, but must be careful to avoid New Matter when amending the claims.

Claims 1, 4-5, 8-9, 11-13, 15-19, 21-25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowles et al (WO0159140).

The claims are drawn to a transgenic cell comprising a nucleic acid comprising SEQ ID NO:1 or comprising a nucleic acid that hybridizes to SEQ ID NO:1 under unspecified conditions, or comprising a nucleic acid that is degenerate as result of the genetic code, wherein the nucleic acid is cDNA, wherein the nucleic acid is genomic DNA, wherein the molecule is overexpressed, wherein the expression of said molecule is down-regulated to reduce glucosyltransferase activity in the cell wherein the cell is null for the said nucleic acid, wherein both sense and antisense molecules are transcribed from the cassette by two different promoters, wherein the RNA molecule forms a double stranded region, wherein the expression cassette is part of a vector, wherein the cell is a eukaryotic plant cell selected from poplar, eucalyptus, Douglas fir, pine, walnut, ash, birch, oak, teak and spruce.

Bowles et al teach a transgenic plant (which inherently comprises a transgenic cell) comprising a nucleic acid molecule which encodes a glucosyltransferase (claim 1) which would inherently hybridize to SEQ ID NO:1, wherein the nucleic acid molecule is cDNA (claim 6), genomic DNA (claim 7), wherein the plant is selected from poplar, eucalyptus, Douglas fir, pine, walnut, ash, birch, oak, teak and spruce (claim 8), the overexpression of glucosyltransferases (page 21 last paragraph, for example), a construct comprising two different promoters (page 20 last 3 paragraphs, for example), and expression of both sense and antisense transcripts (see page 9 and in particular paragraph 4 and page 3, “GTase nucleic acid in sense and/or antisense configuration”), wherein the glucosyltransferase would be down regulated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 11-13, 15-19, 21-25 and 28 rejected under 35 U.S.C. 103(a) as being unpatentable over Bowles et al (WO0159140) in view of Cheuk et al (GenBank accession AY049277).

The claims are drawn to the above, except also wherein the nucleic acid molecule comprises or consists of SEQ ID NO:1 and wherein the sequence glucosylates a monolignol wherein the monolignol is p-coumaryl aldehyde, coniferyl aldehyde, sinapyl aldehyde and coniferyl alcohol.

Bowles et al teach a transgenic plant (which inherently comprises a transgenic cell) comprising a nucleic acid molecule which encodes a glucosyltransferase (claim 1) which would inherently hybridize to SEQ ID NO:1, wherein the nucleic acid molecule is cDNA (claim 6), genomic DNA (claim 7), wherein the plant is selected from poplar, eucalyptus, Douglas fir, pine, walnut, ash, birch, oak, teak and spruce (claim 8), the overexpression of glucosyltransferases (page 21 last paragraph, for example), a construct comprising two different promoters (page 20 last 3 paragraphs, for example), and expression of both sense and antisense transcripts (see page 9 and in particular

paragraph 4 and page 3, "GTase nucleic acid in sense and/or antisense configuration"), wherein the glucosyltransferase would be down regulated.

Bowles et al do not teach SEQ ID NO:1 or the glucosylation of p-coumaryl aldehyde, coniferyl aldehyde, sinapyl aldehyde or coniferyl alcohol.

Cheuk et al (GenBank Accession AY049277) teach a sequence with 100% identity to SEQ ID NO:1 and identify the sequence as a glucosyltransferase. The glucosylation of specific substrates is a property that naturally follows from the enzyme and there would have been a reasonable expectation of success using SEQ ID NO:1 in the present claims.

Given the state of the art and the disclosures by Bowles et al and Cheuk et al, it would have been obvious to one of ordinary skill in the art to use the sequence taught by Cheuk et al, particularly as it was identified as a glucosyltransferase in the methods and transgenic plants taught by Bowles et al as suggested by Bowles et al where the discussion of using various GTases is suggested (see page 3, paragraph 3).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Russell Kallis/
Primary Examiner, Art Unit 1638
November 20, 2008